UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

CIVIL ACTION NO. 10-10951-RWZ

SMITH & NEPHEW, INC.

٧.

INTERLACE MEDICAL, INC.

MEMORANDUM OF DECISION

April 21, 2011

ZOBEL, D.J.

I. Introduction

Plaintiff Smith & Nephew, Inc. ("Smith & Nephew"), brings this action against defendant Interlace Medical, Inc. ("Interlace"), for infringement of U.S. Patent No. 7,226,459, styled the "Reciprocating Rotary Arthroscopic Surgical Instrument" ("the '459 Patent"), a surgical instrument used for cutting and removing tissue, including fibroid and polyp resection. Smith & Nephew alleges that Interlace's device, the MyoSure Tissue Removal Device, which competes with plaintiff's Dyonics Powermax Shaver Handpiece, infringes its patent.

The matter is before the court for construction of several claim terms in the '459 Patent. The parties initially disputed seven terms, but agreed as to two at the hearing. Five are left for the court to construe.

II. Legal Standard

The claims of a patent define the invention. Phillips v. AWH Corp., 415 F.3d

1303, 1312 (Fed. Cir. 2005) (en banc). The construction of patent claims is a matter of law for the court to decide. Markman v. Westview Instruments, Inc., 517 U.S. 370, 372 (1996). In construing patent claims, "the words of a claim are generally given their ordinary and customary meaning;" namely, "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." Phillips, 415 F.3d at 1312-13 (Fed. Cir. 2005) (internal citations omitted).

When the ordinary meaning is not apparent, the court looks to the patent's specification and the prosecution history, which may include evidence of the inventor's and patent office's understanding of the patent. Phillips, 415 F.3d at 1315-17. The presumption that courts are to accord words their ordinary meaning may be overcome only if the patent specification or prosecution history "clearly and deliberately set[s] forth" a different meaning. K-2 Corp. v. Salomon S.A., 191 F.3d 1356, 1363 (Fed. Cir. 1999).

III. Claim Construction and Discussion

A. Agreed Terms

Patent Term	Agreed Construction
"arched bridge shape"	"A curved concave shape"
"chamfered cutting edge"	"A sloping face that is the cutting edge of a cutting element"

B. Disputed Terms

1. Term 1: "A drive coupled to the cutting member to simultaneously rotate...." ('459 Patent, Claim 1)

Term	Court's Construction
"a drive coupled to the cutting member to simultaneously rotate, translate, and reciprocate the cutting member in response to only a rotational force applied to the drive in a single direction"	" a drive joined to a cutting member such that the cutting component simultaneously (i) rotates, (ii) translates, and (iii) reciprocates in response to a rotary motion being applied in a single direction to the drive"
	where "drive" is defined as "a group of components between a motor/power source and a load"

In construing this term, I turn first to the full text of the claim at issue:

What is claimed is [a] surgical instrument, comprising ... a drive coupled to the cutting member to simultaneously rotate, translate, and reciprocate the cutting member in response to only a rotational force applied to the drive in a single direction and to cut tissue during simultaneous rotation and translation of the cutting member.

'459 Patent, Claim 1 (emphasis added).

The issue is the meaning of the term "drive." The parties disagree whether the drive is a single mechanism or is comprised of a number of components.¹ The term appears in all independent claims in the patent, but it is not defined.

The initial disagreement between the parties is whether the claim is a "means plus function" claim under 35 U.S.C. § 112 ¶ 6. A means-plus-function claim element is

¹The parties' proposed constructions appear in the Appendix attached to this decision.

an element in a claim that is expressed "as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof." 35 U.S.C. § 112, ¶ 6. An element is generally presumed to be a "means plus function" element if it contains the word "means" in the description. See Samson Mfg. Corp. v. Austin Precision Products, Inc., No. 09-cv-30027-MAP, 2010 WL 2639864, *5 (D. Mass. 2010). By contrast, a claim that does not use the words "means" triggers a rebuttable presumption that the means-plus-function analysis does not apply. See Lighting World, Inc. v. Birchwood Lighting, Inc., 382 F.3d 1354, 1358 (Fed. Cir. 2004). The term "means" appears nowhere in the '459 Patent. To overcome the rebuttable presumption, Interlace has the burden of proving that the claim fails to "recite sufficiently definite structure" or that is states a "function without reciting sufficient structure for performing that function." Linear Tech. Corp. v. Impala Linear Corp., 379 F.3d 1311, 1319-20 (Fed. Cir. 2004). Interlace has demonstrated neither.

First, the definition of the term "drive" is not seriously disputed. The ordinary and customary meaning of the term as understood by "a person of ordinary skill in the art [of mechanical design]," is "a system or assemblage of components configured so as to enable the transfer of power from a power source ... to a power sink or load...." Docket # 29, Declaration of Dr. Neville Hogan, Ph.D. in Support of Plaintiff's Opening Markman Brief ¶¶ 16-18. See also Phillips v. AWH Corp., 415 F.3d 1303, 1313, (Fed. Cir. 2005) (en banc). Moreover, a generally accepted definition of "drive" is "[t]he equipment used for converting available power into mechanical power suitable for the operation of the machine." IEEE 100 The Authoritative Dictionary of IEEE Standard

Terms, Seventh Addition.

Second, the claims and specification make clear that the drive is comprised of a number of different components. See, e.g., Claims 1, 25, 27, and 28 ("the drive includes a drive member"); Claims 1 and 30 ("the drive includes a translation piece"); Claims 2 and 25 ("the drive [includes] an inner hub drive"); see also Specification 1:28-35 (the drive includes a driver member, translation piece and inner drive hub).

2. Term 2: "Drive Member Attached to the Cutting Member" ('459 Patent, Claim 1)

Term	Court's Construction
	" a member of the drive that does not move relative to the cutting member"

Claim 1 states, in pertinent part:

What is claimed is [a] surgical instrument *** wherein the drive includes a drive member attached to the cutting member, the drive member including a helical groove, and the drive includes a translation piece disposed in the groove such that rotary driving of the drive member results in simultaneous reciprocation of the drive member relative to the translation piece.

'459 Patent, Claim 1 (emphasis added).

At issue is the definition of the term "attached," and specifically, how securely these mechanisms must be affixed to each other. Smith & Nephew contends that the cutting member and the drive member are not so tightly affixed that they do not move relative to each other, while Interlace asserts that the drive member rotates and reciprocates with — but does not move relative to — the cutting member.

Claims 1 and 10 inform one another. Claim 1 broadly recites a "drive member

attached to the cutting member." By contrast, dependent Claim 10 recites a more limited attachment, namely "the instrument of claim 1, wherein the cutting member is attached to the drive member to move rotatably and axially with the drive member." Id., Claim 10. One embodiment in the specification uses the identical language. Id., 1:42-44. Smith & Nephew contends that because Claim 10 requires that the drive member rotate and reciprocate with (i.e., not move relative to) the cutting member, Claim 1 must be interpreted differently, otherwise the two claims would be identical, and the court's construction would render Claim 10 redundant. However, Claim 10 suggests that the cutting member and the drive member are connected such that the cutting member both (1) rotates and, with the drive member, (2) moves along the latter's axis.

In any event, Smith & Nephew's proposed construction, which defines "attached" to mean constraint by "at least one degree of freedom," does not follow. Nothing in the claims suggests attachment by "at least one degree of freedom."

Finally, as Interlace points out, its proposed construction, which includes a stationary drive member, derives from the prosecution history. In Smith & Nephew's response to the Patent Office's 2004 rejection of Claim 1, it expressly defined "attached" as meaning that two components did not "move relative" to each other. See Docket # 31, Ex. K.²

²Smith & Nephew distinguished its claim from the patent issued to Stephen G. Glatzer for a "multi-purpose surgical instrument for subcutaneous use." (U.S. Patent No. 3,995,619) by noting that "the extension 86 is not attached to the cutter element 82 of Glatzer's instrument 10 because the cutter element and the actuator "move relative" to other parts.

3. Term 3: "Cutting Window"

Term	Court's Construction
"Cutting window"	" an opening to provide access to a cutting component"

Claim 15 locates a cutting window "proximate to a tip of the outer tubular member" described in Claim 14. (Claim 15.) In addition, Claim 16 describes its composition: "the cutting window comprises an opening in the outer tubular member exposing the cutting member to tissue" (Claim 16), and Claim 17 describes the shape: "the cutting window comprises a U-shaped proximal end and a saddle-shaped distal end." (Claim 17.) Claim 18 further clarifies that "the cutting window includes a hook." (Claim 18.)³

The parties disagree whether it is a necessary element of the cutting window that the window itself participates in the cutting, or merely provides access to the tissue to be cut.

Interlace proposes that "cutting window" be construed as "ha[ving] a sharpened edge for cutting tissue or holding the tissue to be cut." It is undisputed that the specification (Ex. A at 5:1-10) describes the edge of the cutting window (distal end 173) as "chamfered to provide a sharp edge." However, neither the claims nor the specification refer to the window itself "holding the tissue to be cut" or cutting it. Interlace's construction is further contradicted by Claim 18, which expressly includes a hook and specification 5:5-7 which describes the hook's purpose, to "pierce[] the

³These descriptions also appear in Claims 24 and 32-35.

targeted tissue" and "to hold the tissue as the inner member cuts." <u>Id.</u> Nothing in any of the relevant claims suggests that the cutting window itself does anything more than allow access to a cutting component.

4. Term 4: "Translation Piece"

Term	Court's Construction
"Translation piece"	" a non-reciprocating drive component that enables simultaneous reciprocation, translation, and rotation of a drive member relative to this drive component when a rotary motion is applied to the drive"

The relevant portion of Claim 1 states:

What is claimed is [a] surgical instrument *** wherein the drive includes a drive member attached to the cutting member, the drive member including a helical groove, and the drive includes a translation piece disposed in the groove such that rotary driving of the drive member results in simultaneous reciprocation of the drive member relative to the translation piece.

'459 Patent, Claim 1 (emphasis added).

The term appears also in dependent Claims 8, 9, 19, 21, 22, 30 and 31. The parties disagree whether the translation piece reciprocates (moves) relative to the drive member or remains stationary.

Contrary to Smith & Nephew's interpretation, the plain language of the claim states that "rotary driving of the drive member <u>results in</u> simultaneous reciprocation of the drive member relative to the translation piece." (Emphasis added.) That is, the rotary motion upon the drive member <u>results in</u> the movement of the drive member

relative to the translation piece, <u>i.e.</u>, the translation piece causes reciprocation of the drive member, it does not itself reciprocate. The specification confirms that the drive member, not the translation piece itself, moves. <u>See</u> Specification 4:36-43 ("[]the rotary driver only needs to rotate in one direction and does not require reversal of the rotational direction upon the translation piece reaching the end of one of the helical channels").

5. Term 5: "Coupled"

Term	Court's Construction
"Coupled"	"linked, joined or connected to"

Claim 1 describes the device as including "a drive <u>coupled to</u> the cutting member...." '459 Patent, Claim 1 (emphasis added). At issue is, again, the degree of the connection of the drive member with the cutting member.

The parties agree that "coupled" means "link[ed], join[ed], or connect[ed]." That is all the claim calls for. Indeed, the Federal Circuit has so construed the term. <u>See</u>, e.g., <u>Bradford Co. v. Conteyor N. Am., Inc.</u>, 603 F.3d 1262, 1265 (Fed. Cir. 2010) (construing "coupled" to mean "linked together, connected or joined").

Smith & Nephew's proposed construction attempts to define how securely the components at issue are affixed by reference to degrees of freedom of attachment. It fails because its construction lacks clarity and is not fairly inferred from the claim.

Accordingly, I construe the term to mean "linked, joined or connected to."

April 21, 2011 /s/Rya W. Zobel

DATE

RYA W. ZOBEL UNITED STATES DISTRICT JUDGE

APPENDIX

Term	Smith & Nephew's	Interlace's Proposed
	Proposed Construction	Construction

"a drive coupled to the cutting member to simultaneously rotate, translate, and reciprocate the cutting member in response to only a rotational force applied to the drive in a single direction"

"all components between
(a) a motor/power source
and (b) a cutting
component having a
cutting element, such that
the cutting component
simultaneously (i) rotates,
(ii) translates, and (iii)
reciprocates in response to
a rotary motion being
applied in a single
direction to one of the
components between (a)
and (b)"

where "drive" means "all components between a motor/power source and 7a load" This claim element is a means-plusfunction claim governed by 35 U.S.C. §112 ¶ 6.

Function: "simultaneously rotate, translate, and reciprocate the cutting member in response to only a rotational force applied to the drive in a single direction"

Structure: the inner hub 130, having at one end the drive coupler 120, the helical (or drive) member 150 and translational piece 145

Alternatively, if the claim element is not governed by 35 U.S.C. §112 ¶6, then Interlace would propose the following construction: "a single mechanism that converts an applied rotational force in a single direction into reciprocating and translating forces on the cutting member and that directly transfers the applied rotational force to the cutting member"

"Drive member attached to the cutting member"	"a component of the drive connected to a component including a cutting element such that at least one degree of freedom is constrained between the two components" where "attached" means "a connection in which one component constrains at least one degree of freedom of another component"	"a member of the drive that does not move relative to the cutting member"
"Cutting window"	"an area to enable access to a cutting component"	"a window in the outer tubular member that has a sharpened edge for cutting tissue or holding tissue to be cut"
"Translation piece"	"a drive component located at least in part in a helical groove to enable simultaneous reciprocation, translation, and rotation of a drive member relative to this drive component when a rotary motion is applied to the drive in a single direction"	"a non-reciprocating piece of the drive that converts an applied rotational force into a translational force on the cutting member"
"Coupled"	"a connection in which one component influences motion of a second component, without necessarily constraining any degree of freedom of the second component"	"linked, joined, or connected"